MDHHS
Michigan Department of Health & Human Services

2023-2024 Updated Monovalent COVID-19 Vaccines for Persons 6 Months of Age and Older

October 05, 2023

HOUSEKEEPING

- **How to Ask Questions**
  - Click on the 

 icon found at the bottom part of your screen
  - A box will open where you can type in questions, comments, indicate sound problems, etc.
  - Use this throughout the webinar to ask questions

- **Slides & Recording**
  - This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on our website at: www.michigan.gov/COVIDvaccineprovider

Topics Covered

- COVID-19 Vaccine Ordering and Commercialization
- COVID-19 mRNA Recommendations
- Pfizer Product Information
- Moderna Product Information
- Novavax COVID-19 Recommendations
- Coadministration
- COVID-19 Vaccine Schedules
- CDC’s Interim Clinical Considerations
- Age Transitions and Interchangeability
- EUAs/Product Inserts
- Other Information

COVID-19 Commercialization and Bridge Access Program

Key Points

- Commercialization – transition from vaccine supplied by the government to being **supplied by manufacturers for profit**
- MDHHS **ONLY** has access to public vaccine stock through:
  - Bridge Access Program
  - VFC
- MI-AVP and VFC providers can order vaccine through MDHHS
  - Normal process through MCIR e-ordering
- COVID-19 Vaccines are covered by private/public insurers and provided at no cost to uninsured/underinsured through the Bridge Access Program
- Pharmacies have a separate contract with the federal government to provide vaccines to uninsured

BIVALENT COVID-19 VACCINE INVENTORY and DISPOSAL MANAGEMENT

IMPORTANT: *Bivalent* mRNA (Pfizer-BioNTech or Moderna) COVID-19 vaccines are **NO LONGER authorized for use** in the United States, per the FDA. To minimize the risk of vaccine administration errors, providers should:

- Remove all bivalent mRNA COVID-19 vaccines from storage units immediately, even if they are not expired
- Dispose of **all bivalent mRNA COVID-19 vaccine vials** in accordance with local, state, and federal regulations
- Report all disposed inventory as wastage
  - Disposed inventory should be removed from MCIR inventory using the Non-Return Opened MDV transaction
  - Disposed inventory is reported using the Return/Waste Reporting link in MCIR

ORDERING

- Directly from the manufacturers to obtain private COVID-19 vaccine supply, as you do with other ACIP recommended vaccines
- Through a new temporary program called the Bridge Access Program. This program consists of two components:
  - The first component utilizes existing public health infrastructure including state immunization programs, local health departments, and HRSA-supported health centers to provide COVID-19 vaccines to uninsured adults
  - FOR PHARMACIES: The second component will be implemented through pharmacies that will enable them to continue offering free COVID-19 vaccinations to the uninsured
    - Pharmacies interested in joining can reach out to eTrueNorth for guidance on receiving Bridge COVID-19 vaccine, www.joinetruenorth.com
  - More information about the Bridge Access Program for COVID-19 Vaccines and Treatments can be found online at: Fact Sheet: HHS Announces 'Bridge Access Program For COVID-19 Vaccines and Treatments' to Maintain Access to COVID-19 Care for the Uninsured
- Through the existing Vaccines for Children (VFC) program
  - This program helps provide routinely recommended vaccines to children whose parents or guardians may not be able to afford them
  - VFC Resource Guide (michigan.gov)

Ordering Controls

- COVID-19 vaccines are anticipated to become available by manufacturer over time rather than all at once
- Vaccines will continue to vary in distribution:
  - Moderna and Novavax will be centrally distributed
  - Pfizer will ship directly from the manufacturer
- Controlled ordering (allocations) helps ensure that COVID-19 vaccines are available to all awardees to support their programmatic plans
- MDHHS will regularly self-monitor their vaccine allocations and orders in VTrckS
- As additional COVID-19 vaccines become available, CDC will make updates and adjustments to allocations to align with the ordering activity of awardees

VFC Requirements

- In accordance with signed VFC provider agreements, providers will be expected to carry COVID-19 vaccines for the patient population that they serve
  - Both public and private stock
- MDHHS is working to get information from CDC on the details of this requirement including:
  - Timing
  - Minimum doses on hand
  - Population served

What is expected of Bridge Providers

Patient eligibility

- Permit patients to attest to lack of insurance at point of care
- Collect insurance data through standard screening questions and data collection systems
- Don’t turn away patients due to inability to pay or verify insurance status

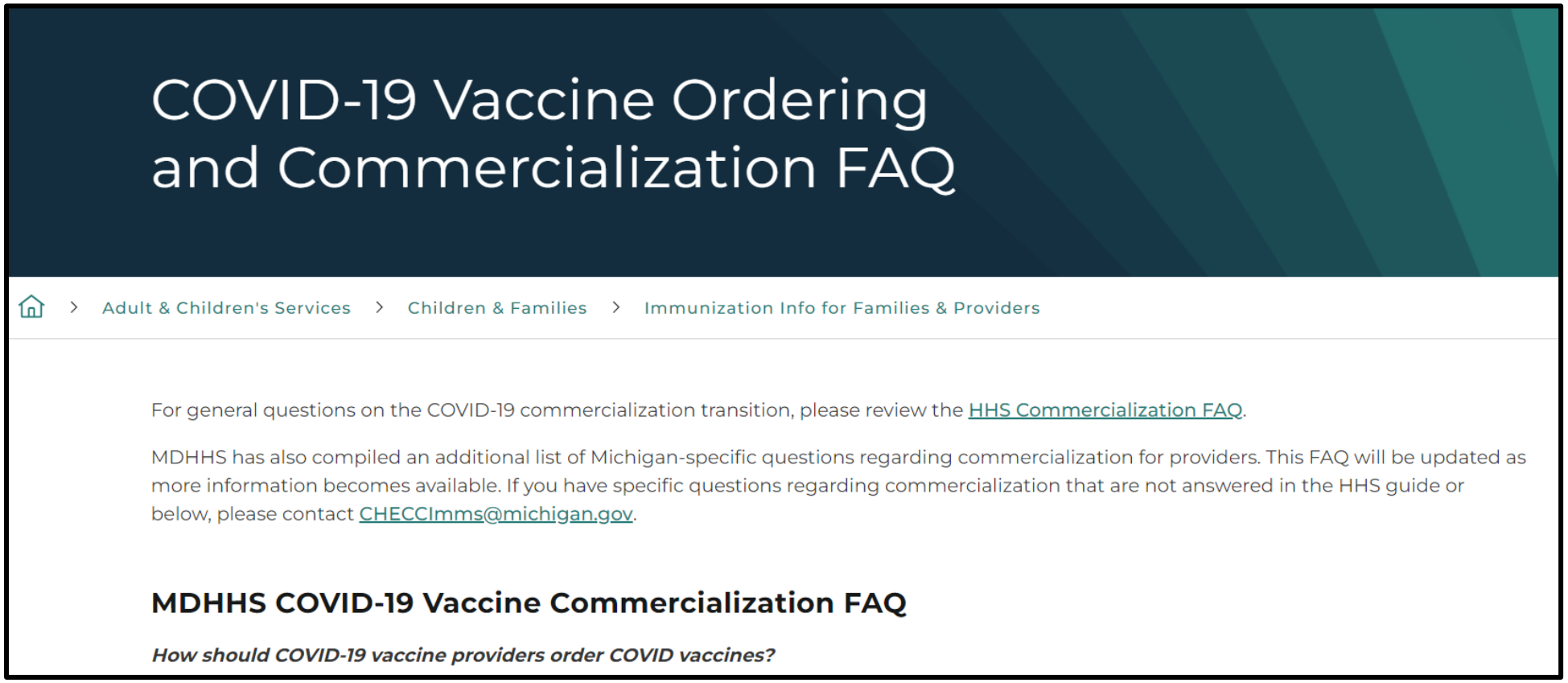
Ordering

- Order vaccines directly through MCIR e-ordering

Administration and Reporting

- Document patient eligibility in MCIR
- Register and submit provider location, contact, and vaccine availability (not inventory) to vaccines.gov

COMMERCIALIZATION FAQ



COVID-19 Vaccine Ordering and Commercialization FAQ

Adult & Children's Services > Children & Families > Immunization Info for Families & Providers

For general questions on the COVID-19 commercialization transition, please review the HHS Commercialization FAQ.

MDHHS has also compiled an additional list of Michigan-specific questions regarding commercialization for providers. This FAQ will be updated as more information becomes available. If you have specific questions regarding commercialization that are not answered in the HHS guide or below, please contact CHECCImms@michigan.gov.

MDHHS COVID-19 Vaccine Commercialization FAQ

How should COVID-19 vaccine providers order COVID vaccines?

www.Michigan.gov/covidvaccineprovider > click on Commercialization FAQ

2023-2024 COVID-19 Vaccine FAQ

As a reminder: The COVID-19 vaccine is now commercialized. As such, MDHHS is ***NOT*** involved in the vast majority of the updated COVID vaccine rollout. MDHHS will only receive COVID-19 vaccine allocations for enrolled VFC and Bridge Access (MI-AVP) providers. At this time, the vaccine allocation received by MDHHS is very small and we do not know when another allocation will be received.

Please check back often as this document will be updated as new guidance is received.

What is commercialization?

The U.S. Government ended distribution of COVID-19 vaccine through the current ordering system on September 12, 2023. COVID-19 vaccine commercialization is the transition from COVID-19 vaccine being supplied by the U.S. Government to the vaccine now being supplied by manufactures for profit. This vaccine is now available through channels like all other ACIP recommended vaccines. It is important to note that with commercialization of COVID-19 vaccines, the State of Michigan will ONLY have federal vaccine allocations for the Vaccines for Children (VFC) program and through the Bridge Access Program to MI-AVP providers.

What is a bridge access provider?

Michigan Bridge Access providers are current MI-AVP providers including local health departments, tribal health organizations, migrant health clinics, and HRSA-supported health centers (Federally Qualified Health Centers- FQHC) to provide COVID-19 vaccines to uninsured and underinsured adults. *Ordering of Bridge COVID-19 vaccine is placed through MI-AVP MCIR E-ordering.*

What is a VFC provider?

Michigan Vaccines for Children (VFC) providers are enrolled into the program by reaching out to their local health department or MDHHS to provide vaccine to uninsured and underinsured children. A child is eligible for the VFC Program if he or she is younger than 19 years of age and is one of the following: Medicaid-eligible, Uninsured, Underinsured or American Indian or Alaska Native.

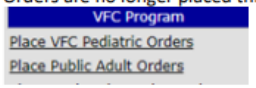
As a VFC provider, am I required to carry COVID-19 vaccine?

All VFC enrolled providers are expected to carry all ACIP recommended immunizations for the population they serve, including the COVID-19 vaccine according to the VFC program requirements acknowledged by signing the VFC provider agreement. Due to the limited number of doses Michigan has on hand, all VFC providers may not be able to order vaccine immediately and should only order the number of doses they expect to use within the next few weeks. MDHHS in collaboration with LHDs, will work alongside the VFC providers as we all navigate this change and what this transition means for each office.

ORDERING

Who can order COVID-19 vaccine through MDHHS?

Michigan MI-AVP/Bridge Access providers and Michigan Vaccines for Children (VFC) providers can order COVID-19 vaccine through MDHHS. Orders for VFC and MI-AVP/Bridge Access COVID-19 vaccines should be placed per normal processes through MCIR e-ordering (see image below). Orders are no longer placed through the MCIR outbreak module.



Where else can I order COVID-19 vaccine?

Providers can order vaccine directly from the manufactures to obtain private COVID-19 vaccine supply, as they do with other ACIP recommended vaccines. Pharmacy providers can also inquire about the Pharmacy component of the bridge access program to obtain vaccine for their uninsured and underinsured adults. Pharmacies interested in joining this program can reach out to eTrueNorth to learn more.

Is ordering for the 2023-2024 COVID-19 vaccine open for VFC or the MI-AVP Bridge Program?

Ordering is currently open for both VFC and MI-AVP Bridge Access Program providers. We received one allocation to be broken apart among the two programs. Orders must be placed separately through MCIR e-ordering.

Can COVID-19 vaccine orders be placed without submitting monthly documentation?

Currently yes. This will change once the vaccine has become integrated into the program on a more normal basis.

Will MDHHS be involved in receiving and distributing the updated COVID-19 vaccines to providers?

MDHHS will receive allocations of COVID-19 vaccine for uninsured and underinsured adults through the Bridge Access Program. These vaccines will be available to Michigan Adult Vaccine Program (MI-AVP) providers which include: Local Health Departments, Federally Qualified Health Centers, Migrant Health Centers, and Tribal Health Centers. COVID-19 Vaccines will also be available through the Vaccines for Children program.

Does HHS allocate the vaccine quantities for each state?

The vaccine is being allocated to each state by HHS. It is also based on product availability.

After the initial allocation, CDC will conduct weekly monitoring of ordering versus allocations using data from the CDC Allocation Balance to implement replenishment allocations based on awardees' ordering history and the availability of additional doses.

If the 12 years and older presentation through the MI-AVP/Bridge Program is ordered, can it also be given to children 12 -18 years that qualify for VFC?

No, providers must maintain separate inventories for MI-AVP/Bridge and VFC.

eparated?

Created 9.26.23

2023-2024-COVID-Vaccine-FAQ.pdf (michigan.gov)

- **Answer:**

  The U.S. Government ended distribution of COVID-19 vaccine through the current ordering system on September 12, 2023. COVID-19 vaccine commercialization is the transition from COVID-19 vaccine being supplied by the U.S. Government to the vaccine now being supplied by manufactures for profit. This vaccine is now available through channels like all other ACIP recommended vaccines. It is important to note that with commercialization of COVID-19 vaccines, the State of Michigan will ONLY have federal vaccine allocations for the Vaccines for Children (VFC) program and through the Bridge Access Program to MI-AVP providers.

Question: What is commercialization?

Question: Who can order COVID-19 vaccine through MDHHS?

- **Answer:**

  Michigan MI-AVP/Bridge Access providers and Michigan Vaccines for Children (VFC) providers can order COVID-19 vaccine through MDHHS. Orders for VFC and MI-AVP/Bridge Access COVID19 vaccines should be placed per normal processes through MCIR e-ordering. Orders are no longer placed through the MCIR outbreak module.

  Ordering is currently open for both VFC and MI-AVP Bridge Access Program providers.

- **Answer**

  Providers can order vaccine directly from the manufactures to obtain private COVID-19 vaccine supply, as they do with other ACIP recommended vaccines. Pharmacy providers can also inquire about the Pharmacy component of the bridge access program to obtain vaccine for their uninsured and underinsured adults. Pharmacies interested in joining this program can reach out to eTrueNorth to learn more.

Question: Where else can I order COVID-19 vaccine?

Question: When will vaccine arrive?

- **Answer**

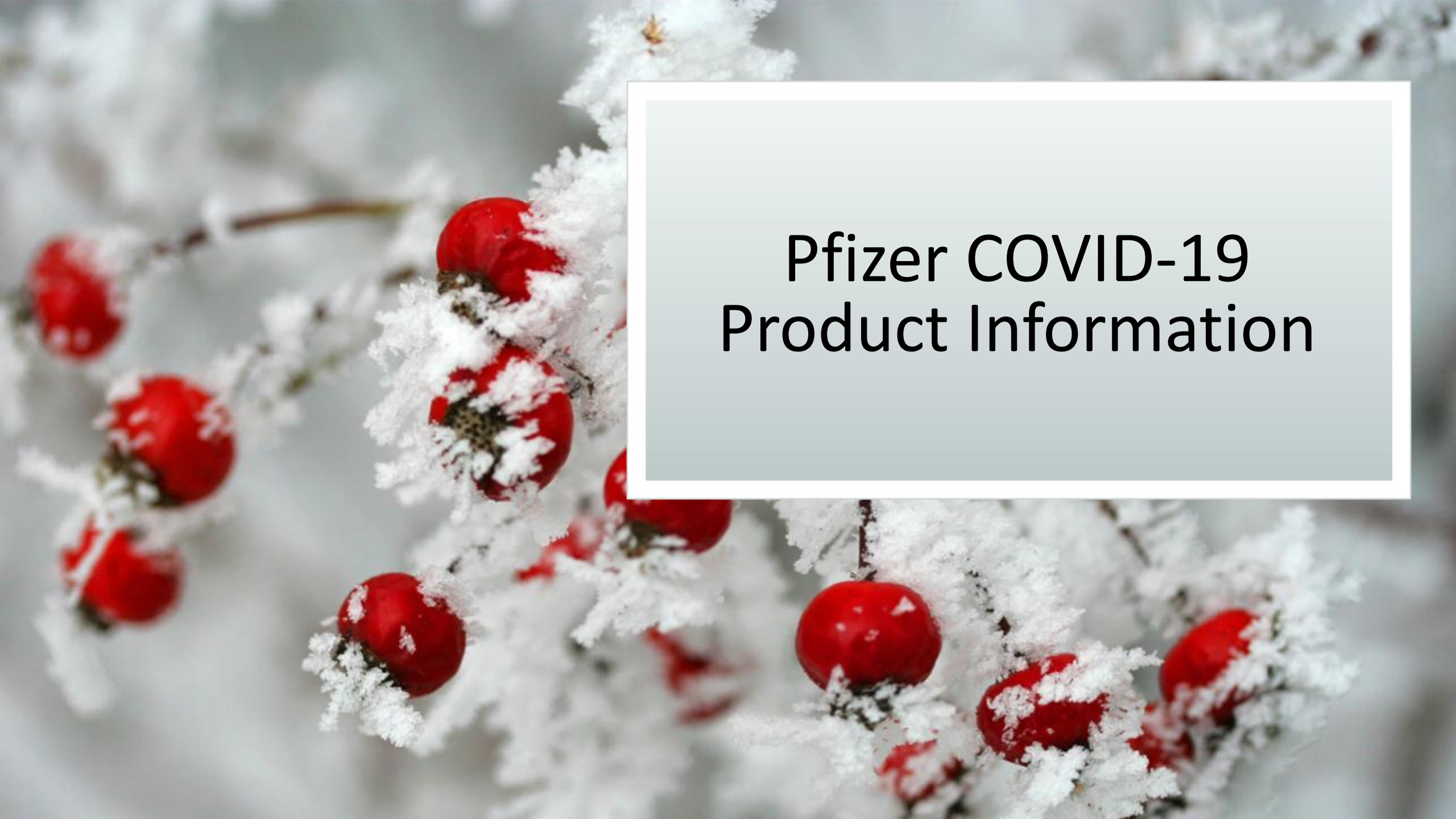
  Please be aware that this time of year there are some delays in receiving regular VFC and MIAVP/Bridge orders. McKesson prioritizes flu vaccine orders and with the addition of all the COVID orders across the country, they are a bit behind. Frozen vaccines (varicella & MMRV) are shipped directly from Merck, not McKesson, and these orders will come separately from the rest of the VFC vaccine order. Pfizer COVID-19 vaccine is also shipped directly from the manufacturer.

COVID-19 mRNA Vaccine Recommendations

COVID-19 Vaccine Recommendations

- ACIP recommends that everyone 6 months and older get an updated 2023-2024 COVID-19 vaccine this fall and winter
  - Updated to include a monovalent component that corresponds to the Omicron variant XBB.1.5
- Everyone ages 5 years and older is recommended to receive 1 dose of a 2023-2024 mRNA COVID-19 vaccine
- Children ages 6 months through 4 years should complete a multi-dose initial series (2 doses of Moderna or 3 doses of Pfizer) with at least one dose of the 2023-2024 COVID-19 vaccine
- People who are moderately or severely immunocompromised should complete a 3-dose initial series with at least one dose of the 2023-2024 COVID-19 vaccine and may receive 1 or more additional 2023-2024 COVID-19 vaccine doses
- **Bivalent mRNA COVID-19 vaccines are no longer recommended in the U.S.**
  - Updated mRNA COVID-19 Vaccines to Better Protect Against Currently Circulating Variants

PowerPoint Presentation (cdc.gov)



Pfizer COVID-19 Product Information

Pfizer & BioNTech COVID-19 vaccines (2023-2024 formula)

Age Group	12 years and older	12 years and older*	5 through 11 years	6 months through 4 years
Cap Color & Label Border	Gray 	N/A 	Blue 	Yellow 
Dilution	DO NOT DILUTE	New! Prefilled Syringe*	DO NOT DILUTE	DILUTE BEFORE USE Diluent amount per vial: 1.1 mL†
Number of Doses	Single Dose Vial	Single Dose	Single Dose Vial	3 doses per vial
Dose	30 mcg	30 mcg	10 mcg	3 mcg
Dose Volume	0.3 mL	0.3 mL	0.3 mL	0.3 mL

†*Diluent: sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.*

* Pfizer anticipates launching a limited quantity of a prefilled syringe presentation for individuals 12 years of age & older pending regulatory approval/authorization.

Pfizer EUA Healthcare 6m-11y 9.11.2023 (michigan.gov)
ShowLabeling.aspx (pfizer.com)

Pfizer & BioNTech COVID-19 vaccines (2023-2024 formula)

Age Group	12 years and older Single Dose Vial	12 years and older Prefilled Syringe*	5 through 11 years Single Dose Vial	6 months through 4 years Multiple Dose Vial
ULT Freezer (-90ºC to -60ºC)	**18 months**	**9 months**	**12 months**	**12 months**
Freezer (-25°C to -15°C)	**DO NOT STORE**	**DO NOT STORE**	**DO NOT STORE**	**DO NOT STORE**
Refrigerator (2°C to 8°C)	**10 weeks**	**10 weeks**	**10 weeks**	**10 weeks**
Room Temperature (8°C to 25°C)	12 hours prior to use	See additional information	12 hours prior to use	12 hours prior to first puncture
After First Puncture (2°C to 25°C)	N/A**	N/A	N/A**	Discard after 12 hours

N/A: Not applicable

* Pfizer anticipates launching a limited quantity of a prefilled syringe presentation for individuals 12 years of age & older pending regulatory approval/authorization.
** Use immediately, discard vial and any excess volume.
Regardless of storage condition, vaccine should not be used past the expiration date printed on the label.

Pfizer EUA Healthcare 6m-11y 9.11.2023 (michigan.gov)
ShowLabeling.aspx (pfizer.com)

Updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vac
At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, administra
BioNTech COVID-19 Vaccine products.

Distributed in:

Ages: 6 months through 4 years
Multiple-dose vial:
yellow cap and yellow label

Ages: 5 through 11 years
Single dose vial:
blue cap and blue label

Storage and Handling

Find additional guidance on storing vaccine properly at:

- CDC *Vaccine Storage and Handling Toolkit*
- Pfizer-BioNTech COVID-19 Vaccine | FDA
- Comirnaty |
- Pfizer-BioNTe

Ages	6 months through 4 years	5 through 11 years	12 y
Supplied in:	3-dose multiple-dose vial (MDV)	Single-dose vial (SDV)	Single-
Cap and/or label color:	Yellow cap and yellow label	Blue cap and blue label	Gray ca gray la
Storage temperature before puncture	**Between**: ▪ -90°C and -60°C (-130°F and -76°F) until the expiration da ▪ 2°C and 8°C (36°F and 46°F) for up to 10 weeks ▪ 8°C and 25°C (46°F and 77°F) for up to 12 hours prior to t **Do not store between -25°C and -15°C (-13°F and 5°F).** **NOTE:** The beyond-use date (10 weeks) replaces the manufactur Always use the earliest date. Do NOT use vaccine after the expira		
Thawing frozen vaccine	**Between:** ▪ 2°C and 8°C (36°F and 46°F) for up to 2 hours OR ▪ Up to 25°C (77°F) for 30 minutes		

09/29/2023 CS321570-AN

Updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vacci
At-A-Glance

Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- Vaccine Administration Resource Library | CDC
- Pfizer-BioNTech
- Pfizer-BioNTech

Preparation

- If the vaccine is frozen, thaw before use.
- Check the vial label to ensure the expiration date has not passed.
  - Use Pfizer-BioNTech expiration date tool at lotexpiry.cvdvaccine.com
- Product for ages 6 months through 4 years: mix with diluent.
  - Mix vial with 1.1 mL diluent. If using the MDV for the first time, record the date and time the vial was punctured. **NOTE:** The beyond-use time of 12 hours replaces the manufacturer Always use th **the expiratio**
- Products for ag older: **Do NOT**
- **Do NOT shake** withdrawing va
- Refer to packag instructions.

Administration

- COVID-19 vaccines may be administered at the same clinical visit as other routinely recommended vaccines.
- If using a MDV, Do NOT "pool vaccine" from more than 1 vial to obtain a dose. If a full dose cannot be withdrawn, discard the MDV and any remaining vaccine.
- If using a SDV, v dose, discard th save used SDVs.
- Administer intra

Recipient's Age	Dosage	Route	Needle gauge and length
6 months through 4 years of age	0.3 mL/3 *µg*	IM injection	22–25 gauge, 1"*
5 through 11 years of age	0.3 mL/10 *µg*L	IM injection	22–25 gauge, 1"*
12 years of age and older	0.3 mL/30 *µg*	IM injection	22–25 gauge, 1–1.5"*§

* A 5/8 inch needle may be used if administering the vaccine in the deltoid muscle AND the skin is stretched tightly and the su ages 1–18 years and adults ages 19 years and older who weigh less than 130 pounds.

† The deltoid muscle in the upper arm may be used if the muscle mass is adequate for children ages 1–2 years.

Updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine
At-A-Glance

Scheduling Doses

The number of recommended 2023–24 COVID-19 vaccine doses varies by age, vaccine, vaccination history, and the presence of moderate or severe immune compromise. Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for detailed clinical guidance when scheduling doses, and the Interim COVID-19 Immunization Schedule for summary information.

Contraindications, Precautions, and Post-Vaccination Observation

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered.

Contraindications

History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine

Precautions

History of:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- 30 minutes for persons with:
  - A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
  - A history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine, if receiving the same vaccine type
- 15 minutes: All other persons

Documentation

Document each recipient's vaccine administration information:

- **Medical record:** The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
- **Vaccination record for recipient:** Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or health care professional
- **Immunization information system (IIS):** Report the vaccination to the appropriate state/local IIS.

Report Adverse Events to the Vaccine Adverse Event Reporting System (VAERS)

- Adverse events that occur in a recipient following administration of any licensed or authorized COVID-19 vaccine should be reported to VAERS, including:
  - Vaccine administration errors, whether or not associated with an adverse event
  - Serious adverse events, irrespective of attribution to vaccination
  - Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
  - Cases of myocarditis
  - Cases of pericarditis
  - Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

Pfizer-BioNTech COVID-19 Vaccine At A Glance: Updated 2023-2024 Formula (cdc.gov)

6 Months Through 4 Years of Age

Updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine

2023–24 Formula Vaccine Presentation	Diluent	Dose/Injection Amount	Route
Multidose vial with yellow cap and yellow label	1.1 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent	0.3 mL/3 μg	Intramuscular (IM) injection

Purpose

To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where authorized under state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess children 6 months through 4 years of age for vaccination with the 2023–24 Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:

People who are NOT moderately or severely immunocompromised*

COVID-19 vaccination history† (regardless of COVID-19 vaccine formula)	Schedule for administration of 2023-24 Pfizer-BioNTech COVID-19 Vaccine
Unvaccinated	Give a 3-dose initial series. Administer: ▪ Dose 1 now ▪ Dose 2 at least 3–8 weeks after Dose 1‡ ▪ Dose 3 at least 8 weeks after Dose 2
1 previous dose of any Pfizer-BioNTech COVID-19 Vaccine (Dose 1)§	Complete series. Administer: ▪ Dose 2 at least 3–8 weeks after Dose 1‡ ▪ Dose 3 at least 8 weeks after Dose 2
2 doses of any Pfizer-BioNTech COVID-19 Vaccine (Doses 1 and 2)§¶	Complete series. Administer: ▪ Dose 3 at least 8 weeks after Dose 2
3 or more doses Pfizer-BioNTech COVID-19 Vaccine, **NOT** including at least 1 dose of 2023–24 COVID-19 vaccine§	Give 1 dose at least 8 weeks (2 months) after the previous dose.
3 or more doses Pfizer-BioNTech COVID-19 Vaccine, **INCLUDING** at least 1 dose of 2023–24 COVID-19 vaccine§	No further doses are indicated.

* Persons with a recent SARS-CoV-2 infection may consider delaying vaccination by 3 months from symptom onset or positive test (if infection was asymptomatic).

† COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination of the three, unless otherwise specified.

‡ An 8-week interval between the first and second COVID-19 vaccine (Moderna, Novavax, and Pfizer-BioNTech) doses might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

§ People who are recommended to receive a multidose mRNA series for initial vaccination (i.e., children ages 6 months–4 years and people who are moderately or severely

[6 Months Through 4 Years of Age : Updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine - Standing Orders for Administering Vaccine (cdc.gov)]

5 Years of Age and Older

Updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine

2023–24 Formula Vaccine Presentation	Age	Diluent	Dose/Injection Amount	Route
Single-dose vial with blue cap and blue label	5 through 11 years	None	0.3 mL/10 μg	Intramuscular (IM) injection
Single-dose vial with gray cap and gray label	12 years and older	None	0.3 mL/30 μg	Intramuscular (IM) injection
Manufacturer-filled syringe	12 years and older	None	0.3 mL/30 μg	Intramuscular (IM) injection

Purpose

To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where authorized under state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess children 5 years of age and older for vaccination with the 2023–24 Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:

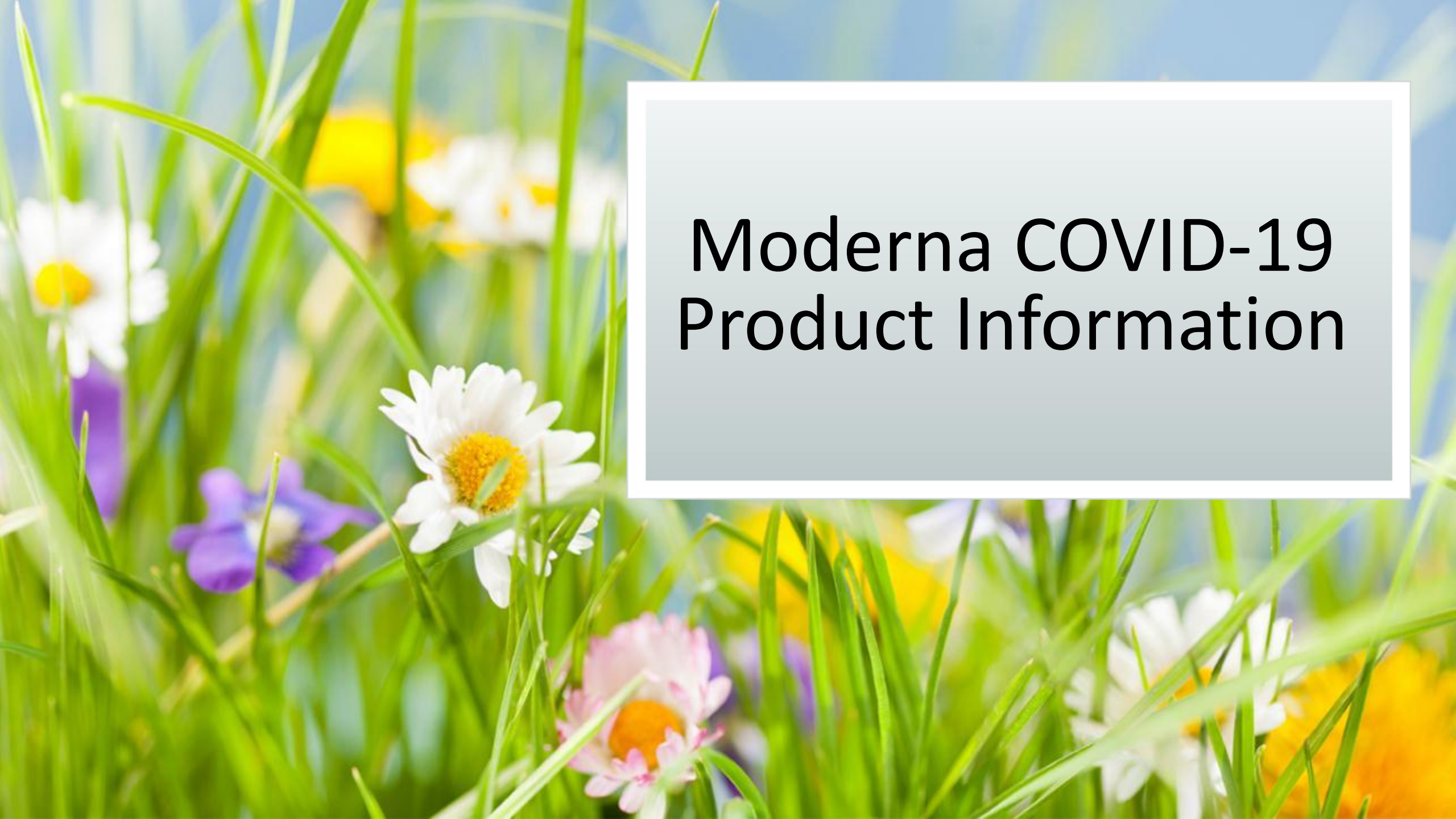
People who are NOT moderately or severely immunocompromised*

COVID-19 vaccination history† (regardless of COVID-19 vaccine formula)	Schedule for administration of 2023-24 Pfizer-BioNTech COVID-19 Vaccine
Unvaccinated	Give 1 dose now.
Any number of previous doses of COVID-19 vaccine, **NOT** including at least 1 dose of 2023–24 COVID-19 vaccine	Give 1 dose at least 8 weeks (2 months) after the previous dose.
Any number of previous doses COVID-19 vaccine, **INCLUDING** at least 1 dose of 2023–24 COVID-19 vaccine	No further doses are indicated.

* Persons with a recent SARS-CoV-2 infection may consider delaying vaccination by 3 months from symptom onset or positive test (if infection was asymptomatic).

† COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination of the three, unless otherwise specified.

[5 Years of Age and Older: Updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine - Standing Orders for Administering Vaccine (cdc.gov)]


Moderna COVID-19
Product Information

Ages	6 Months through 11 Years	12 Years and Older	12 Years and Older
Supplied In	 2023-24 Product	 2023-24 Product	 2023-24 Product
Cap and/or label color	Dark blue cap and **green label**	Dark blue cap and **blue label**	N/A
Diluent	**Do Not Dilute**		
Dose Volume & Dose	0.25 mL/25mcg (IM)	0.5 mL/50mcg (IM)	0.5 mL/50mcg (IM)
Freezer	-50°C to -15°C (-58°F to 5°F) until the expiration date		
Refrigerator	2°C to 8°C (36°F to 46°F) for up to 30 days		
Total Time at Room Temp	8°C to 25°C (46°F to 77°F) for a total of 24 hours Discard vial or syringe and unused vaccine after 24 hours		
Refrigerator Thaw Time (Do not refreeze)	45 minutes for single dose vial or 1 hour for syringe at 2°C to 8°C (36°F to 46°F) Let stand at room temp for 15 min before administering		
Room Temp Thaw Time (Do not refreeze)	15 minutes for single dose vial or 45 minutes for syringe at 15°C to 25°C (59°F to 77°F)		

Note: The beyond-use date replaces the manufacturer's expiration date but **NEVER** extends it. Always use the earliest date. Do NOT use vaccine after the expiration date or beyond-use date

Moderna Storage and Handling

Moderna EUA Healthcare 6m-11y 09.11.2023 (michigan.gov)

download (fda.gov)

Updated (2023-24 Formula) Moderna COVID-19 Vaccine

At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, administration
COVID-19 Vaccine products.

Distributed in:

Ages: 6 months through 11 years
Single-dose vial:
Dark blue cap and green label

Ages: 12 y
Single dos
Dark blue
Manufactu

Storage and Handling

Find additional guidance on storing vaccine properly at:

- CDC *Vaccine Storage and Handling Toolkit*
- Moderna COVID-19 Vaccine | FDA
- Spikevax | FDA
- Moderna COVID

Ages	6 months through 4 years	12 years and older
Supplied in:	Single-dose vial (SDV)	Single-dose vial (SDV)
Cap and/or label color:	Dark blue cap and green label	Dark blue cap and blue label
Storage temperature before puncture	**Between**: ▪ -50°C and -15°C (-58°F and 5°F) until the expiration date ▪ 2°C and 8°C (36°F and 46°F) for up to 30 days ▪ 8°C and 25°C (46°F and 77°F) for a total of 24 hours. Discard 24 hours. **NOTE:** The beyond-use date (30 days) replaces the manufactu it. Always use the earliest date. Do NOT use vaccine after the e	
Thawing frozen vaccine	**Between:** ▪ 2°C and 8°C (36°F and 46°F) for 45 minutes. Let stand at roo temperature (between 15°C and 25°C [59°F and 77°F]) for 15 minutes. OR ▪ 15°C and 25°C (59°F and 77°F) for 15 minutes	

Updated (2023-2024 Formula Moderna COVID-19 Vaccine

At-A-Glance

Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly

- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- Vaccine Administration Resource Library | CDC
- Moderna C
- Moderna C

Preparation

If the vaccine is frozen, allow to thaw. Before preparing the vaccine, let vacc
Do NOT refreeze thawed vaccine.

- Check the vial label to ensure the expiration date has not passed.
  - Use Moderna expiration date tool at https://modernacovid19global.com/vial-lookup
- Do not sha
- If using an
- Refer to pa instructior

Administration

- COVID-19 vaccines may be administered at the same clinical visit as other routinely recommended vaccines.
- If using an dose, disca save used
- Administer

Recipient's Age	Dosage	Route	Needle gaug and length
6 months through 11 years of age	0.25 mL/25 *ug*	IM injection	22–25 gauge, 1
12 years of age and older	0.5 mL/50 *ug*	IM injection	22–25 gauge, 1–1.5"*

* A 5/8 inch needle may be used if administering the vaccine in the deltoid muscle AND the skin is stretched tightly an ages 1–18 years and adults ages 19 years and older who weigh less than 130 pounds.

†The deltoid muscle in the upper arm may be used if the muscle mass is adequate in children ages 1–2 years.

‡ The vastus lateralis muscle in the anterolateral thigh may be used as an alternate site.

Updated (2023-2024 Formula) Moderna COVID-19 Vaccine

At-A-Glance

Scheduling Doses

The number of recommended 2023–24 COVID-19 vaccine doses varies by age, vaccine, vaccination history, and the presence of moderate or severe immune compromise. Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for detailed clinical guidance when scheduling doses, and the Interim COVID-19 Immunization Schedule for summary information.

Contraindications, Precautions, and Post-Vaccination Observation

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered.

Contraindications

History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine

Precautions

History of:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- 30 minutes for persons with:
  - A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
  - A history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine, if receiving the same vaccine type
- 15 minutes: All other persons

Documentation

Document each recipient's vaccine administration information:

- **Medical record:** The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
- **Vaccination record for recipient:** Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or health care professional
- **Immunization information system (IIS):** Report the vaccination to the appropriate state/local IIS.

Report Adverse Events to the Vaccine Adverse Event Reporting System (VAERS)

- Adverse events that occur in a recipient following administration of any licensed or authorized COVID-19 vaccine should be reported to VAERS, including:
  - Vaccine administration errors, whether or not associated with an adverse event
  - Serious adverse events, irrespective of attribution to vaccination
  - Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
  - Cases of myocarditis
  - Cases of pericarditis
  - Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

Moderna COVID-19 Vaccine At A Glance: Updated 2023-2024 Formula (cdc.gov)

6 Months Through 4 Years of Age

Updated (2023–2024 Formula) Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine

2023–24 Formula Vaccine Presentation	Dose/Injection Amount	Route
Single-dose vial with dark blue cap and green label	0.25 mL/25 *µg*	Intramuscular (IM) injection

Purpose

To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where authorized under state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess children 6 months through 4 years of age for vaccination with the 2023–24 Moderna COVID-19 Vaccine based on the following criteria:

Children who are NOT moderately or severely immunocompromised*

COVID-19 vaccination history† (regardless of COVID-19 vaccine formula)	Schedule for administration of 2023-24 Moderna COVID-19 Vaccine
Unvaccinated	Give a 2-dose initial series. Administer: ▪ Dose 1 now ▪ Dose 2 at least 4–8 weeks after Dose 1‡
1 previous dose of any Moderna COVID-19 Vaccine (Dose 1)§	Give Dose 2 at least 4–8 weeks after Dose 1‡
2 or more doses Moderna COVID-19 Vaccine, **NOT** including at least 1 dose of 2023–24 COVID-19 vaccine§¶	Give 1 dose at least 8 weeks (2 months) after the previous dose.
2 or more doses Moderna COVID-19 Vaccine, **INCLUDING** at least 1 dose of 2023–24 COVID-19 vaccine§¶	No further doses are indicated.

* Persons with a recent SARS-CoV-2 infection may consider delaying vaccination by 3 months from symptom onset or positive test (if infection was asymptomatic).
† COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination of the three, unless otherwise specified.
‡ An 8-week interval between the first and second COVID-19 vaccine (Moderna, Novavax, and Pfizer-BioNTech) doses might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.
§ People who are recommended to receive a multidose mRNA series for initial vaccination (i.e., children ages 6 months–4 years and people who are moderately or severely immunocompromised) should receive all doses from the same manufacturer. However, in the following exceptional situations a different age-appropriate COVID-19 vaccine product may be administered: the same vaccine is not available, the person would otherwise not complete the vaccination series, or the person starts but is unable to complete a vaccination series with the same vaccine due to a contraindication.
¶ For children who have received 1 Moderna and 1 Pfizer-BioNTech vaccines of any formulation, follow a 3-dose schedule. A third dose of either Moderna vaccine or Pfizer-BioNTech vaccine should be administered at least 8 weeks after the second dose.

[6 Months Through 4 Years of Age • Updated (2023–2024 Formula) Moderna COVID-19 Vaccine - Standing Orders for Administering Vaccine (cdc.gov)]

5 Years of Age and Older

Updated (2023–2024 Formula) Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine

2023–24 Formula Vaccine Presentation	Age	Dose/Injection Amount	Route
Single-dose vial with dark blue cap and green box on the label	5 through 11 years	0.25 mL/25 *µg*	Intramuscular (IM) injection
Single-dose vial with dark blue cap and blue box on the label	12 years and older	0.50 mL/50 *µg*	Intramuscular (IM) injection
Manufacturer-filled syringe	12 years and older	0.50 mL/50 *µg*	Intramuscular (IM) injection

Purpose

To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

Where authorized under state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess children 5 years of age and older for vaccination with the 2023–24 Moderna COVID-19 Vaccine based on the following criteria:

People who are NOT moderately or severely immunocompromised*

COVID-19 vaccination history† (regardless of COVID-19 vaccine formula)	Schedule for administration of 2023-24 Moderna COVID-19 Vaccine
Unvaccinated	Give 1 dose now.
Any number of previous doses of COVID-19 vaccine, **NOT** including at least 1 dose of 2023–24 COVID-19 vaccine	Give 1 dose at least 8 weeks (2 months) after the previous dose.
Any number of previous doses COVID-19 vaccine, **INCLUDING** at least 1 dose of 2023–24 COVID-19 vaccine	No further doses are indicated.

* Persons with a recent SARS-CoV-2 infection may consider delaying vaccination by 3 months from symptom onset or positive test (if infection was asymptomatic).
† COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination of the three, unless otherwise specified.

[5 Years of Age and Older • Updated (2023–2024 Formula) Moderna COVID-19 Vaccine • Standing Orders for Administering Vaccine (cdc.gov)]

Novavax COVID-19 Recommendations

NOVAVAX

- October 3, 2023, FDA amended the emergency use authorization (EUA) of Novavax COVID-19 vaccine, adjuvanted to include the 2023-2024 formula
- **Individuals Previously Vaccinated with Any COVID-19 Vaccine:** one dose of Novavax (2023-2024 formula) at least 2 months after receipt of the last previous dose of original monovalent or bivalent COVID-19 vaccine
- **Individuals Not Previously Vaccinated with Any COVID-19 Vaccine:** 2 doses of Novavax COVID-19 vaccine (2023-2024 formula) administered 3 weeks apart
- Waiting for CDC's Interim Clinical Considerations to be updated with further guidance on immunocompromised individuals
- **Novavax COVID-19 Vaccine, Adjuvanted (original monovalent) is no longer authorized for use in the United States**

Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) Fact Sheet for Healthcare Providers Administering Vaccine (michigan.gov)

Novavax Storage and Handling

- Supplied as carton containing 2 multi-dose vials. Each multi-dose vial contains 5 doses of 0.5mL each
- Store the unpunctured multi-dose vaccine vial in a refrigerator between 2 to 8°C (36 to 46°F)
- Do not freeze
- Protect from light
- Gently swirl the multi-dose vial before each dose. Do not shake
- After first puncture, hold the vial between 2 to 25°C (36 to 77°F) for up to 12 hours Discard the vial 12 hours after the first puncture
- Administer Intramuscularly (IM)

Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) Fact Sheet for Healthcare Providers Administering Vaccine (michigan.gov)

COVID-19 Vaccine Coadministration

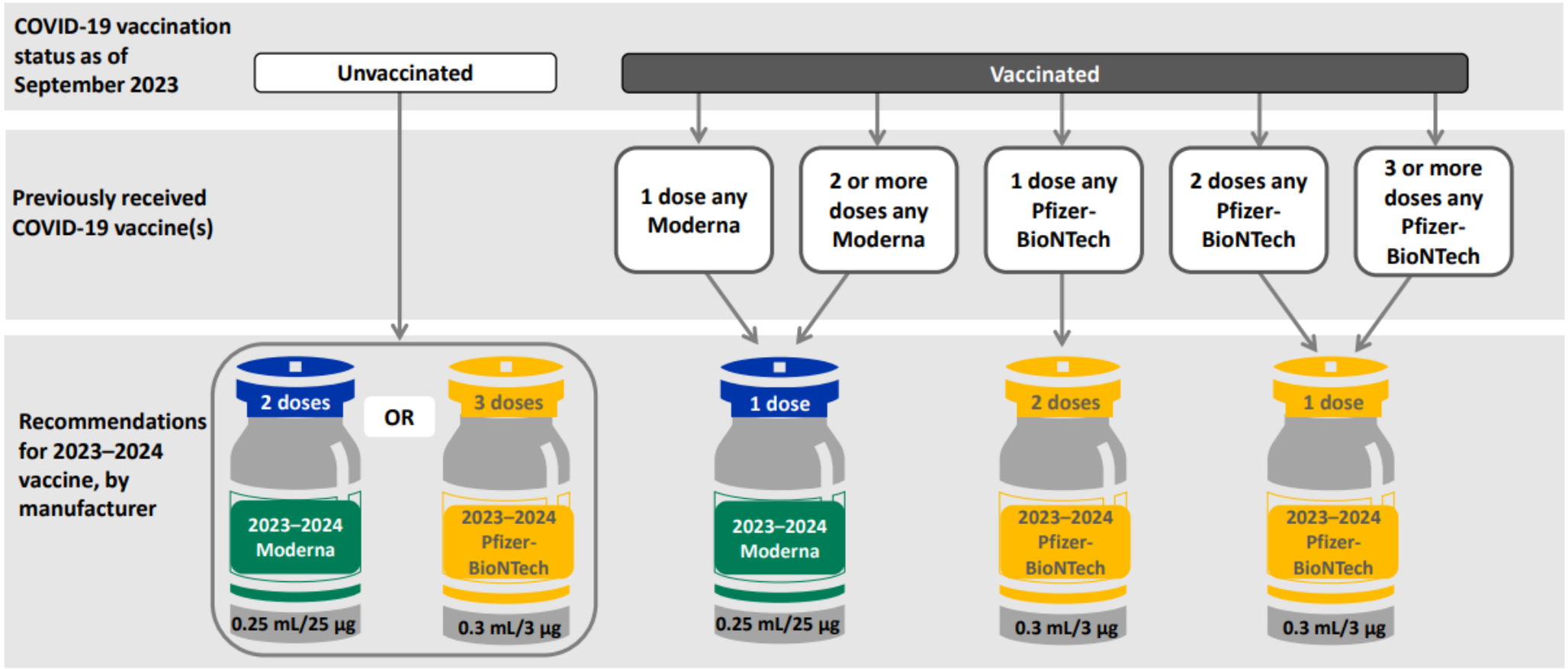
COADMINISTRATION

- COVID-19 vaccines **may be administered without regard to timing of other vaccines**
- This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site
  - Best practices for multiple injections include:
    - Label each syringe with the name and the dosage (amount) of the vaccine, lot number, initials of the preparer, and exact beyond-use time, if applicable
    - Separate injection sites by 1 inch or more, if possible
    - Administer the COVID-19 vaccine and vaccines that may be more likely to cause a local reaction in different limbs, if possible

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

COVID-19 Vaccine Schedules

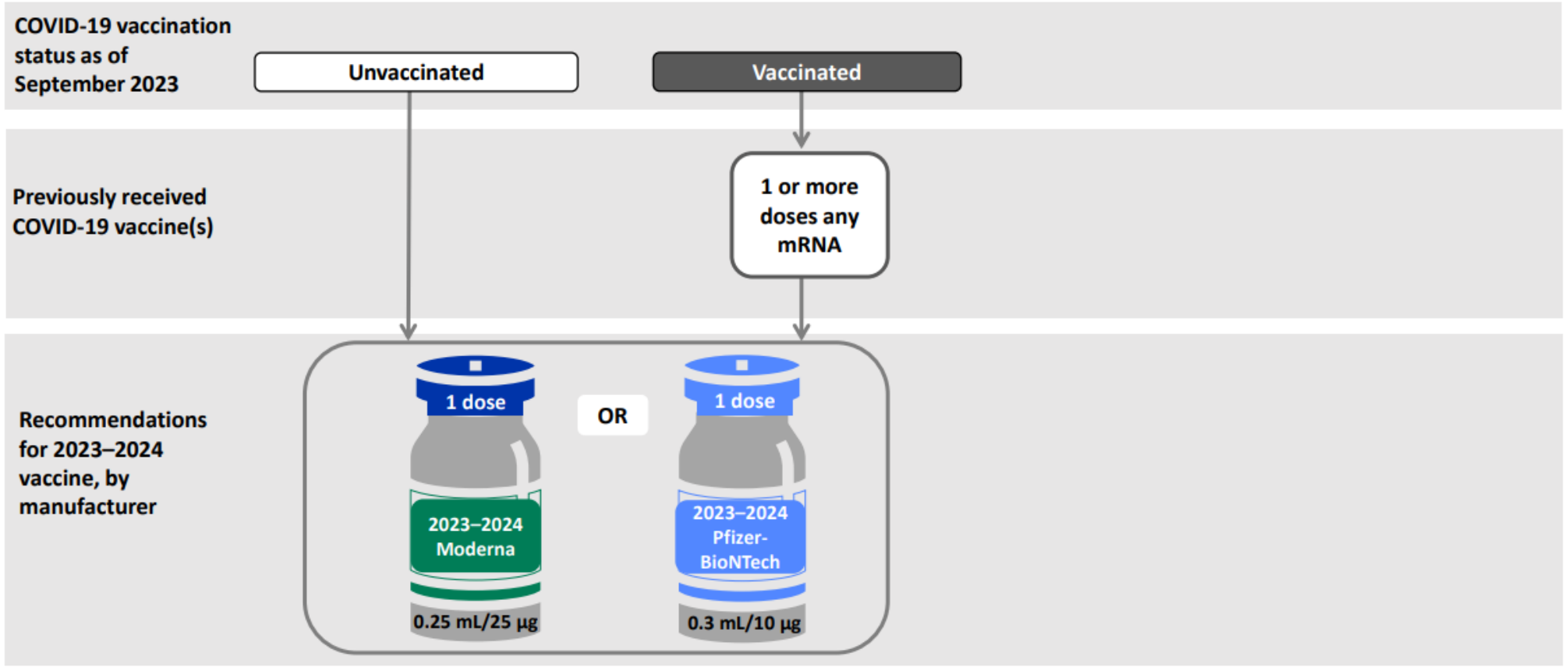
Recommended 2023-2024 COVID-19 mRNA Vaccines for People Who are **NOT Immunocompromised Aged 6 Months Through 4 Years**



***For information about administration intervals and people who transition from age 4 years to age 5 years during an mRNA vaccination series, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.**

Clinical Guidance for COVID-19 Vaccination | CDC

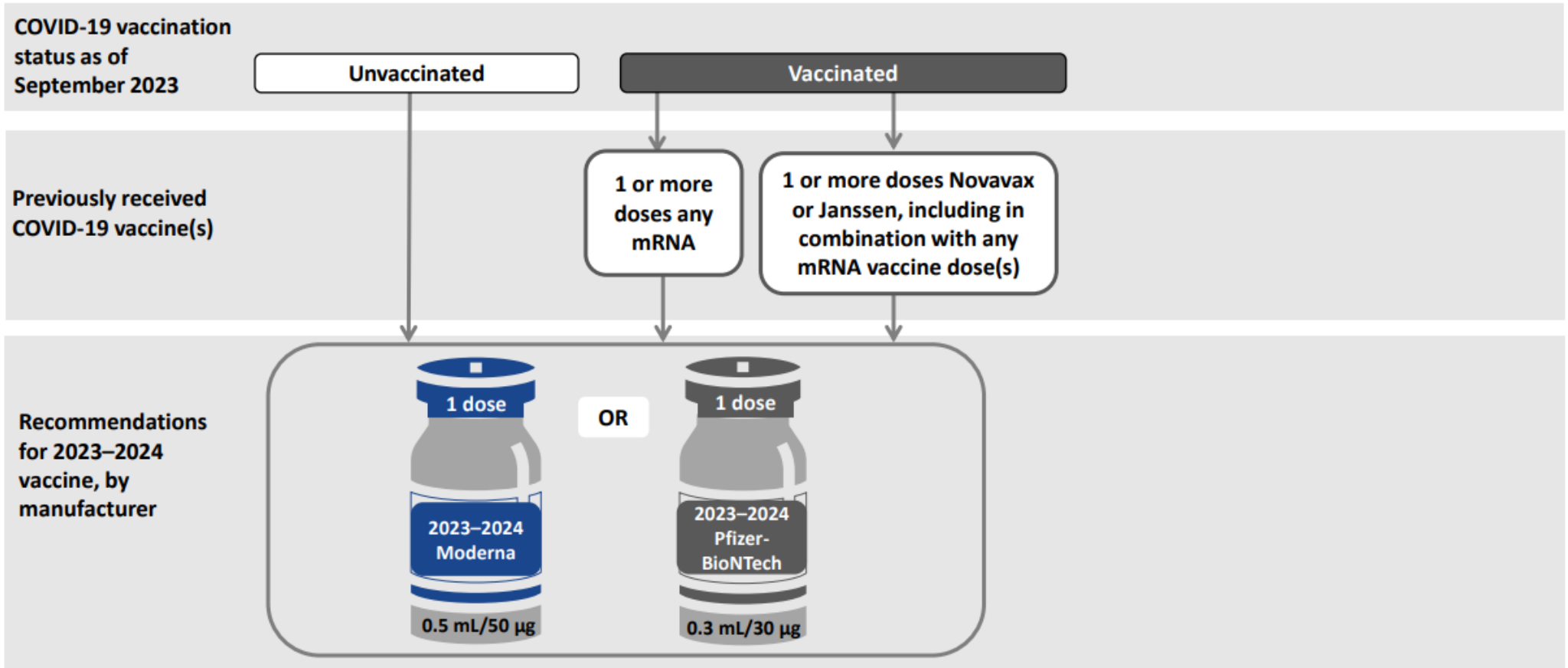
Recommended 2023-2024 COVID-19 mRNA Vaccines for
People Who are **NOT Immunocompromised Aged 5 Through 11 Years**



*For information about administration intervals and people who transition from age 4 years to age 5 years during an mRNA vaccination series, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

Clinical Guidance for COVID-19 Vaccination | CDC

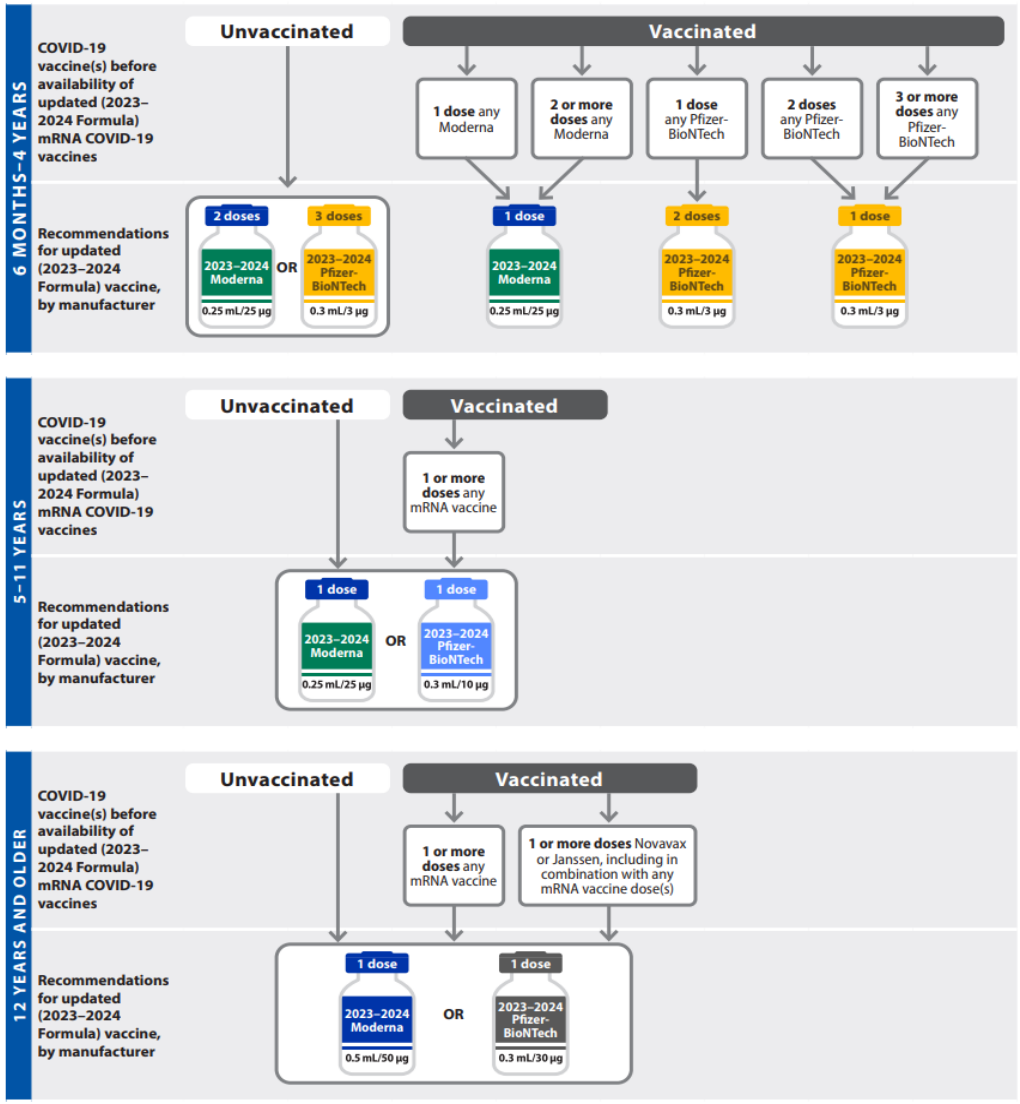
Recommended 2023-2024 COVID-19 mRNA Vaccines for
People Who are **NOT Immunocompromised Aged 12 Years and Older**



*For information about administration intervals, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 vaccines.

Clinical Guidance for COVID-19 Vaccination | CDC

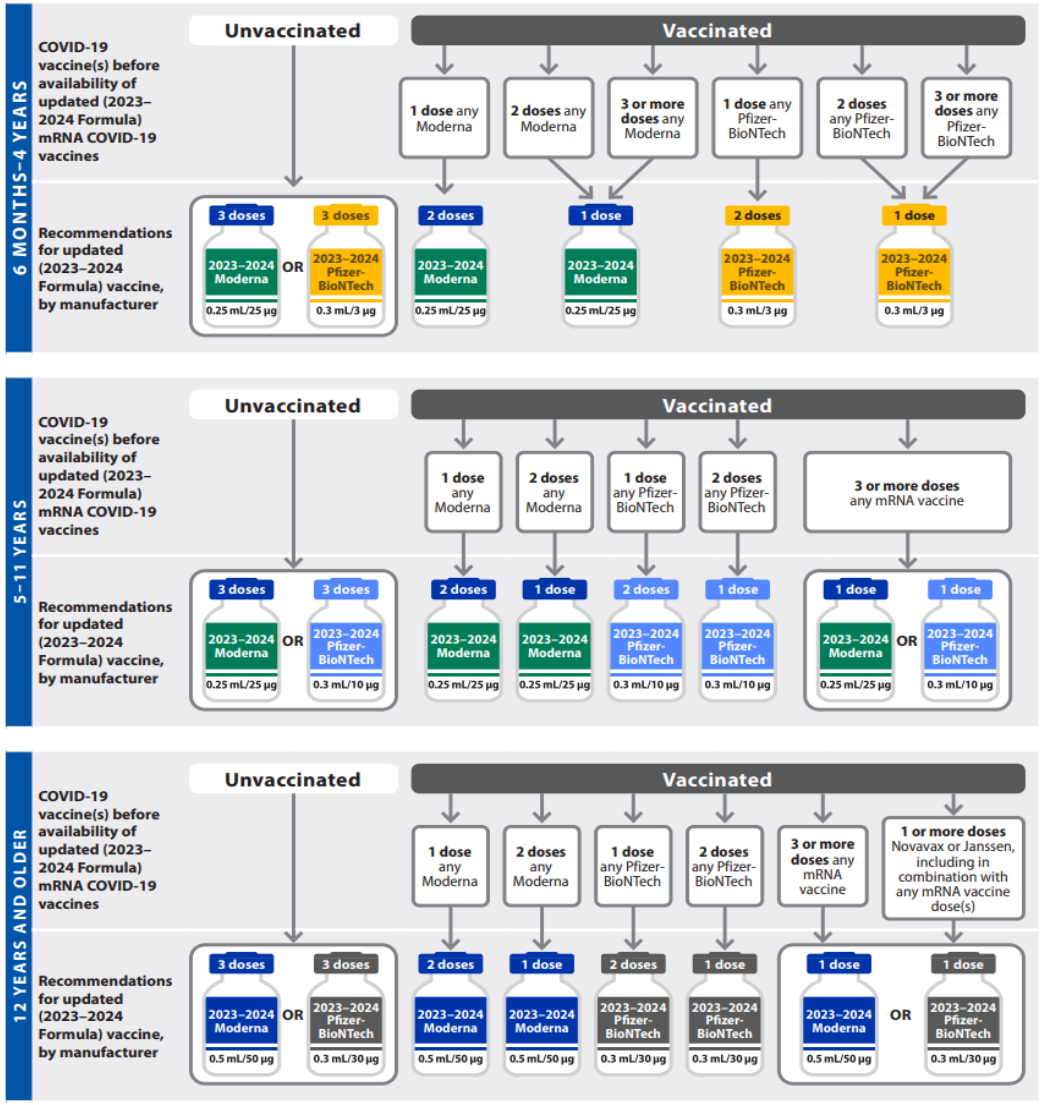
Recommended updated (2023–2024 Formula) mRNA COVID-19 vaccines for people who **NOT** moderately or severely immunocompromised*†



*For information about administration intervals and people who transition from age 4 years to age 5 years, see Table 1 in the Interim Clinical Considerations for Use of COVID-19 Vaccines.
†Vaccines before availability of updated (2023–2024 Formula) mRNA COVID-19 vaccines refers to previous dose(s) of Original monovalent mRNA or bivalent mRNA vaccine, or a combination of the two; or Novavax COVID-19 Vaccine or Janssen COVID-19 Vaccine, alone or in combination with any mRNA vaccine doses.

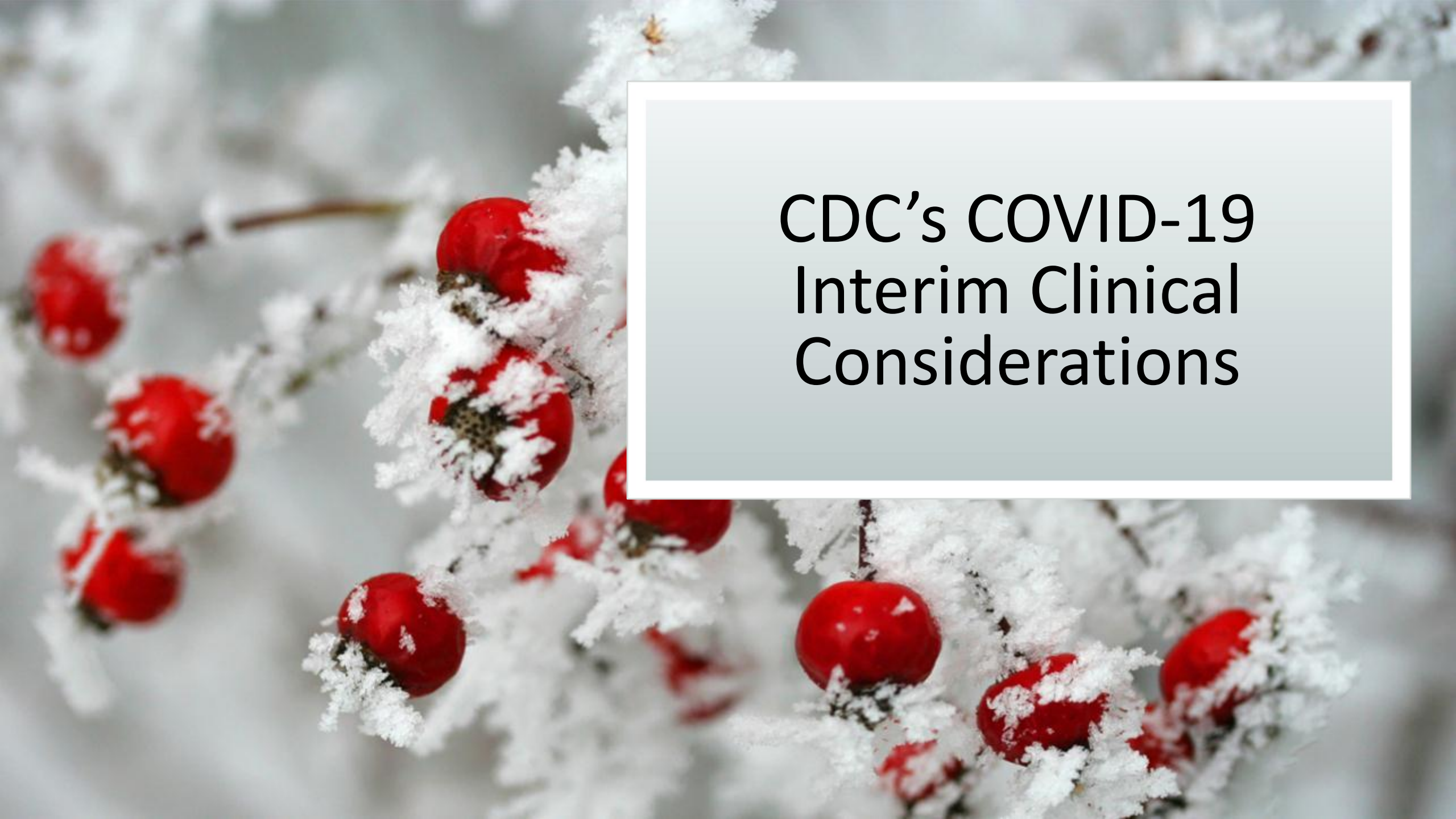
[COVID-19 vaccines 2023-2024 NOT immunocompromised (cdc.gov)]

Recommended updated (2023–2024 Formula) mRNA COVID-19 vaccines for people who **ARE** moderately or severely immunocompromised*†



*For information about administration intervals, people who transition from age 4 years to age 5 years or age 11 years to age 12 years during an mRNA vaccination series, and administration of additional dose(s), see Table 2 in Interim Clinical Considerations for Use of COVID-19 Vaccines.
†Vaccines before availability of updated (2023–2024 Formula) mRNA COVID-19 vaccines refers to previous dose(s) of Original monovalent mRNA or bivalent mRNA vaccine, or a combination of the two; or Novavax COVID-19 Vaccine or Janssen COVID-19 Vaccine, alone or in combination with any mRNA vaccine doses.

[COVID-19 vaccines 2023-2024 ARE immunocompromised (cdc.gov)]



CDC's COVID-19 Interim Clinical Considerations

Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States

Print

Summary of recent changes (last updated September 15, 2023):

- Recommendations for use of the 2023–2024 formulations of Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine:
  - Everyone ages 5 years and older is recommended to receive 1 dose of updated (2023–2024 Formula) mRNA COVID-19 vaccine
  - Children ages 6 months–4 years
    - › Initial vaccination: should receive either 2 doses of updated (2023–2024 Formula) Moderna or 3 doses of updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine
    - › Received previous mRNA doses: need 1 or 2 doses of updated (2023–2024 Formula) Moderna or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine, depending on the number of prior doses
  - People who are moderately or severely immunocompromised
    - › Initial vaccination: should receive a 3-dose series of updated (2023–2024 Formula) Moderna or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine
    - › Received previous mRNA doses: need 1 or 2 doses of updated (2023–2024 Formula) Moderna or updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 vaccine, depending on the number of prior doses
    - › May receive 1 or more additional updated (2023–2024 Formula) mRNA COVID-19 vaccine doses
  - Bivalent mRNA COVID-19 vaccines are no longer recommended in the United States
- Updated guidance for COVID-19 vaccination and myocarditis or pericarditis
- Updated guidance for COVID-19 vaccination and Multisystem Inflammatory Syndrome (MIS) in children (MIS-C) and in adults (MIS-A)
- Reorganization and consolidation of sections on contraindications and precautions, including allergic reactions to COVID-19 vaccines

Overview of COVID-19 vaccination

These clinical considerations provide information to healthcare professionals and public health officials on use of COVID-19 vaccines. They are informed by:

- Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC)
- COVID-19 vaccine approval (licensure) under a Biologics License Application (BLA) or authorization under an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA)
- CDC's Emergency Use Instructions (EUI) for FDA-approved vaccines
- Emergency Use Listing (EUL) of COVID-19 vaccines by the World Health Organization (WHO)
- ACIP's General Best Practice Guidelines for Immunization
- Expert opinion

Table 1. Recommended COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised by COVID-19 vaccination history, September 15, 2023

Updated (2023–2024 Formula) mRNA COVID-19 vaccines

Ages 6 months–4 years

COVID-19 vaccination history prior to updated (2023–2024 Formula) mRNA vaccine*	Updated (2023–2024 Formula) mRNA vaccine	Number of updated (2023–2024 Formula) mRNA vaccine doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna	2	0.25 mL/25 ug	Dark blue cap; green label	Dose 1 and Dose 2: 4–8 weeks†
	Pfizer-BioNTech	3	0.3 mL/3 ug	Yellow cap; yellow label	Dose 1 and Dose 2: 3–8 weeks† Dose 2 and Dose 3: At least 8 weeks
1 dose any Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; green label	4–8 weeks after last dose†
2 or more doses any Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; green label	At least 8 weeks after last dose
1 dose any Pfizer-BioNTech	Pfizer-BioNTech	2	0.3 mL/3 ug	Yellow cap; yellow label	Dose 1: 3–8 weeks after last dose† Dose 1 and Dose 2: At least 8 weeks
2 doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/3 ug	Yellow cap; yellow label	At least 8 weeks after last dose
3 or more doses any Pfizer-BioNTech	Pfizer-BioNTech	1	0.3 mL/3 ug	Yellow cap; yellow label	At least 8 weeks after last dose

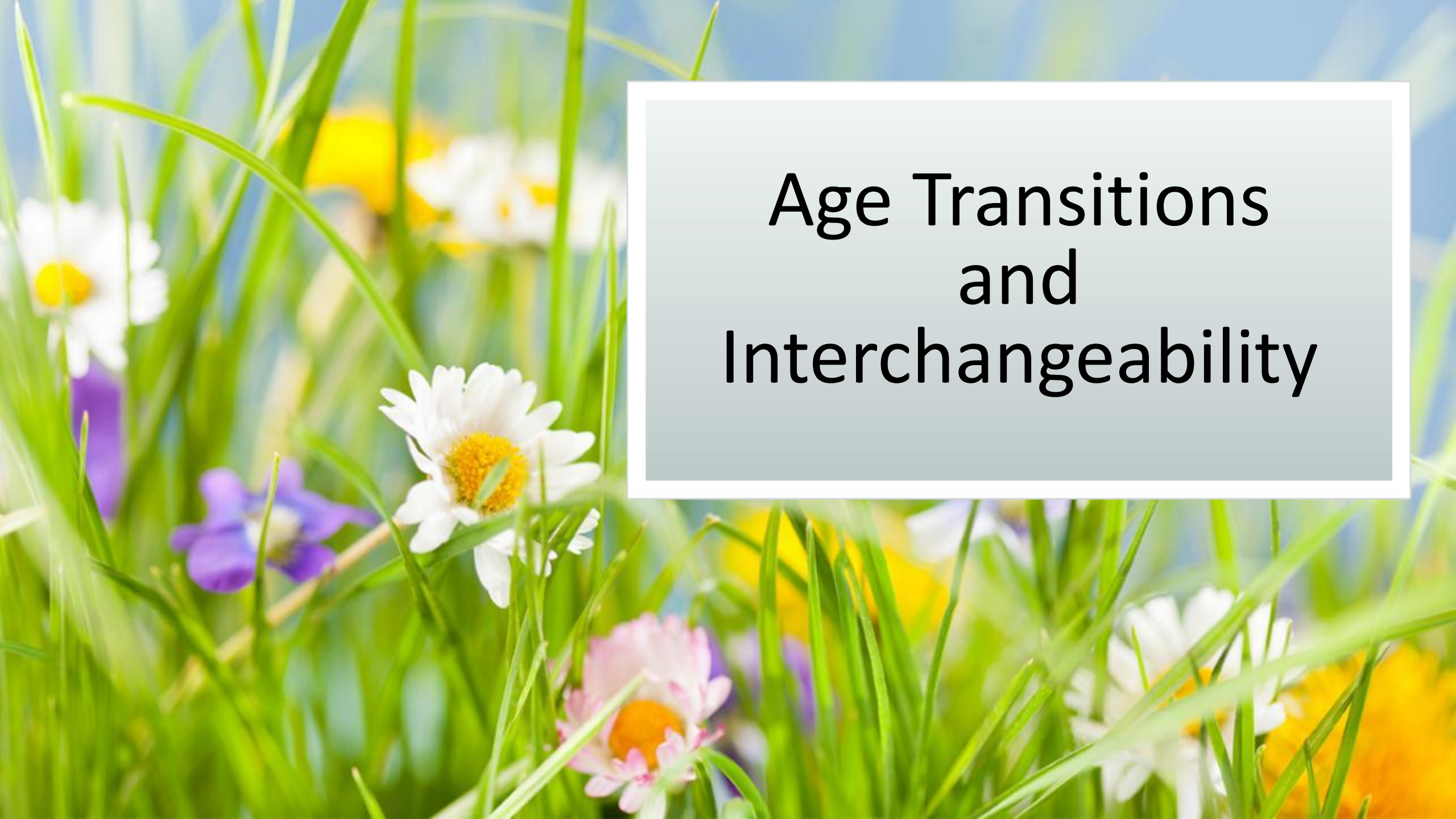
Ages 5–11 years‡

COVID-19 vaccination history prior to updated (2023–2024 Formula) mRNA vaccine*	Updated (2023–2024 Formula) mRNA vaccine	Number of updated (2023–2024 Formula) mRNA doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
Unvaccinated	Moderna	1	0.25 mL/25 ug	Dark blue cap; green label	—
	Pfizer-BioNTech	1	0.3 mL/10 ug	Blue cap; blue label	—
1 or more doses any mRNA	Moderna OR	1	0.25 mL/25 ug	Dark blue cap; green label	At least 8 weeks after last dose
	Pfizer-BioNTech	1	0.3 mL/10 ug	Blue cap; blue label	At least 8 weeks after last dose

Ages 12 years and older

COVID-19 vaccination history prior to updated (2023–2024 Formula) mRNA vaccine*	Updated (2023–2024 Formula) mRNA vaccine	Number of updated (2023–2024 Formula) mRNA doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors§	Interval between doses
Unvaccinated	Moderna	1	0.5 mL/50 ug	Dark blue cap; blue label	—
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	—
1 or more doses any mRNA	Moderna OR	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose
1 or more doses Novavax or Janssen, including in combination with any mRNA vaccine dose(s)	Moderna OR	1	0.5 mL/50 ug	Dark blue cap; blue label	At least 8 weeks after last dose
	Pfizer-BioNTech	1	0.3 mL/30 ug	Gray cap; gray label	At least 8 weeks after last dose

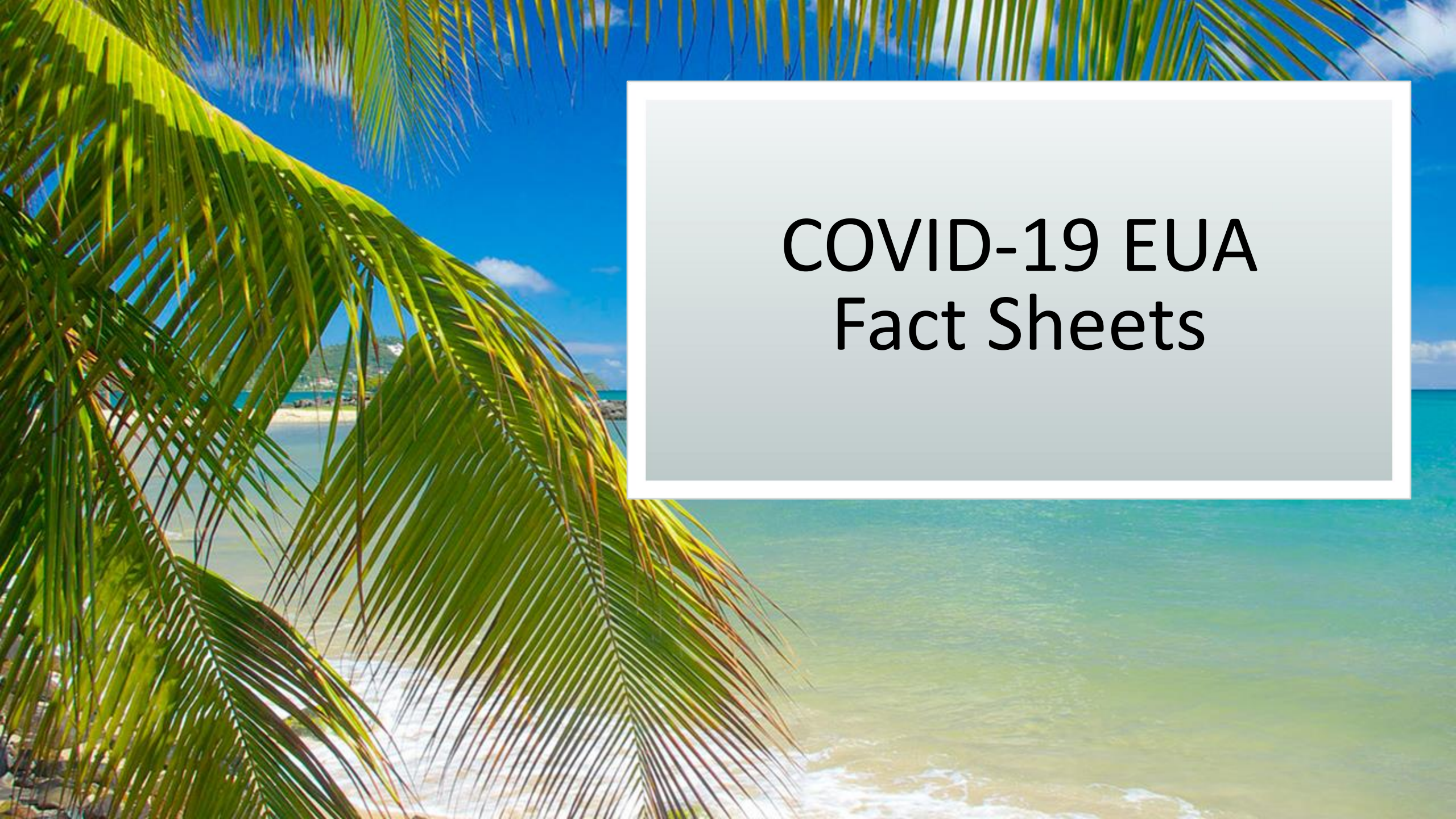
Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC


Age Transitions
and
Interchangeability

TRANSITIONING FROM A YOUNGER TO OLDER AGE GROUP

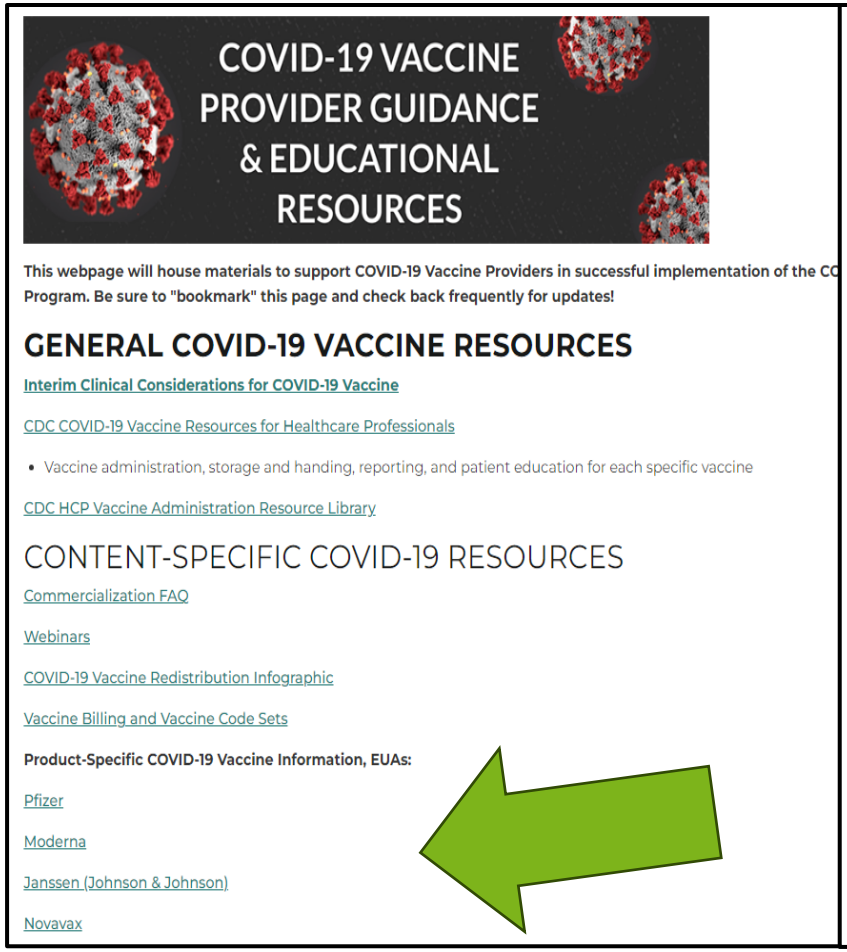
- CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination (Table 1 and Table 2)
- If a person moves to an older age group between vaccine doses, they should receive the vaccine product and dosage for the older age group for all subsequent doses with one exception:
  - The EUA provides that children who transition from age 4 years to age 5 years during the Pfizer-BioNTech COVID-19 vaccination series complete the 3-dose series with updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine for ages 6 months–4 years, 0.3 mL/3 ug (yellow cap; yellow label)
- In addition, the EUA provides that children who transition from age 4 years to age 5 years during the Moderna vaccination series complete the 2-dose series; there is no dosage change

Clinical Guidance for COVID-19 Vaccination | CDC



COVID-19 EUA Fact Sheets

Provider Guidance and Education



COVID-19 VACCINE PROVIDER GUIDANCE & EDUCATIONAL RESOURCES

This webpage will house materials to support COVID-19 Vaccine Providers in successful implementation of the CO
Program. Be sure to "bookmark" this page and check back frequently for updates!

GENERAL COVID-19 VACCINE RESOURCES

Interim Clinical Considerations for COVID-19 Vaccine

CDC COVID-19 Vaccine Resources for Healthcare Professionals

- Vaccine administration, storage and handing, reporting, and patient education for each specific vaccine

CDC HCP Vaccine Administration Resource Library

CONTENT-SPECIFIC COVID-19 RESOURCES

Commercialization FAQ

Webinars

COVID-19 Vaccine Redistribution Infographic

Vaccine Billing and Vaccine Code Sets

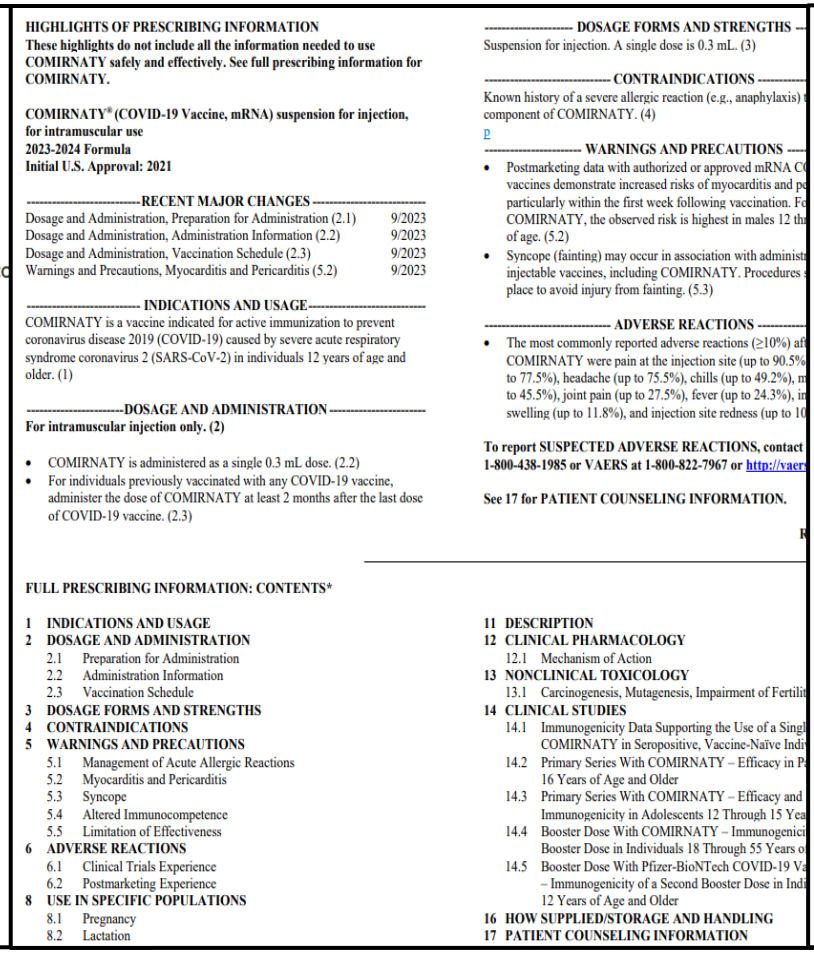
Product-Specific COVID-19 Vaccine Information, EUAs:

Pfizer

Moderna

Janssen (Johnson & Johnson)

Novavax



HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use COMIRNATY safely and effectively. See full prescribing information for COMIRNATY.

COMIRNATY® (COVID-19 Vaccine, mRNA) suspension for injection, for intramuscular use
2023-2024 Formula
Initial U.S. Approval: 2021

----------RECENT MAJOR CHANGES----------

Dosage and Administration, Preparation for Administration (2.1)	9/2023
Dosage and Administration, Administration Information (2.2)	9/2023
Dosage and Administration, Vaccination Schedule (2.3)	9/2023
Warnings and Precautions, Myocarditis and Pericarditis (5.2)	9/2023

----------INDICATIONS AND USAGE----------

COMIRNATY is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older. (1)

----------DOSAGE AND ADMINISTRATION----------

For intramuscular injection only. (2)

- COMIRNATY is administered as a single 0.3 mL dose. (2.2)
- For individuals previously vaccinated with any COVID-19 vaccine, administer the dose of COMIRNATY at least 2 months after the last dose of COVID-19 vaccine. (2.3)

---------- DOSAGE FORMS AND STRENGTHS ----------

Suspension for injection. A single dose is 0.3 mL. (3)

---------- CONTRAINDICATIONS ----------

Known history of a severe allergic reaction (e.g., anaphylaxis) t
component of COMIRNATY. (4)
p

---------- WARNINGS AND PRECAUTIONS ----------

- Postmarketing data with authorized or approved mRNA C
vaccines demonstrate increased risks of myocarditis and pe
particularly within the first week following vaccination. Fo
COMIRNATY, the observed risk is highest in males 12 th
of age. (5.2)
- Syncope (fainting) may occur in association with administ
injectable vaccines, including COMIRNATY. Procedures
place to avoid injury from fainting. (5.3)

---------- ADVERSE REACTIONS ----------

- The most commonly reported adverse reactions (≥10%) af
COMIRNATY were pain at the injection site (up to 90.5%
to 77.5%), headache (up to 75.5%), chills (up to 49.2%), m
to 45.5%), joint pain (up to 27.5%), fever (up to 24.3%), in
swelling (up to 11.8%), and injection site redness (up to 10

To report SUSPECTED ADVERSE REACTIONS, contact 1-800-438-1985 or VAERS at 1-800-822-7967 or http://vaer

See 17 for PATIENT COUNSELING INFORMATION.

FULL PRESCRIBING INFORMATION: CONTENTS*

Information for Recipients and Caregivers
SPIKEVAX (pronounced SPĪK-văx)
(COVID-19 Vaccine, mRNA)
(2023-2024 Formula)

Please read this information sheet before getting SPIKEVAX. This summary is not intended to take the place of talking with your healthcare provider. If you have questions or would like more information, please talk with your healthcare provider.

What is SPIKEVAX?
SPIKEVAX is a vaccine to protect you against COVID-19. SPIKEVAX is for people 12 years of age and older. Vaccination with SPIKEVAX may not protect all people who receive the vaccine.

SPIKEVAX does not contain SARS-CoV-2, the virus that causes COVID-19. SPIKEVAX cannot give you COVID-19.

Who should not get SPIKEVAX?
You should not get SPIKEVAX if you had:

- a severe allergic reaction after a previous dose of SPIKEVAX, Moderna COVID-19 Vaccine (Original monovalent), or Moderna COVID-19 Vaccine, Bivalent[1]
- a severe allergic reaction to any ingredient of this vaccine (see **What are the ingredients in SPIKEVAX?**)

What should I tell my healthcare provider?
Tell your healthcare provider about all of your medical conditions, including if you:

- have any allergies
- had a severe allergic reaction after receiving a previous dose of any COVID-19 vaccine
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received any other COVID-19 vaccine
- have ever fainted in association with an injection

COVID-19 Vaccine Provider Guidance and Educational Resources (michigan.gov)

Comirnaty (fda.gov)

SPIKEVAX (fda.gov)

Other Info

What to do if there is an administration error and what resource can I use for help?

Table B. Interim recommendations for COVID-19 vaccine administration errors and deviations

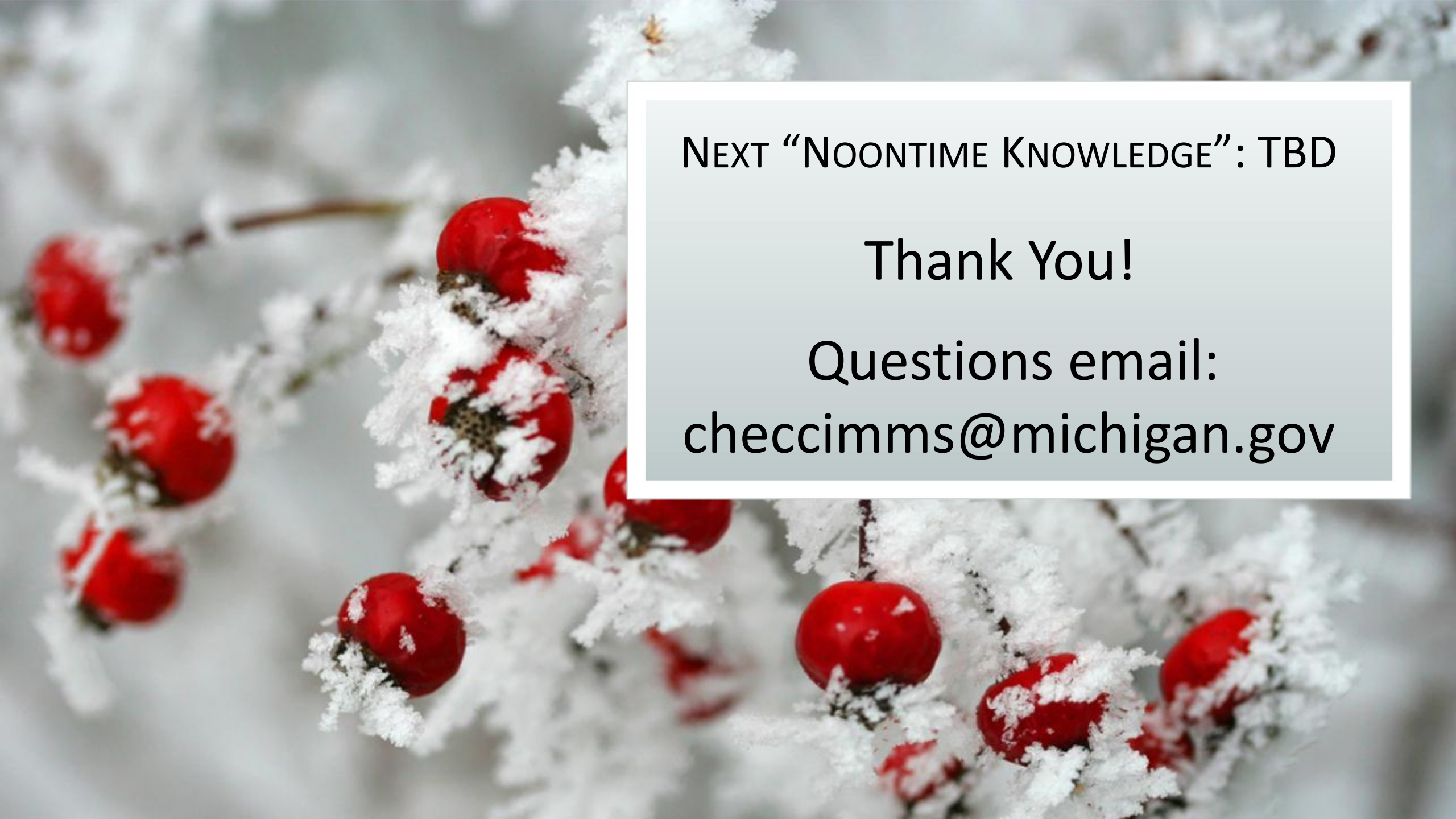
Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle or vastus lateralis muscle)	• Do not repeat dose.
	• Incorrect route (e.g., subcutaneous)	• Do not repeat dose. • Inform the recipient of the potential for local and systemic adverse events.
Age	• Unauthorized age group (recipients younger than age 6 months)	• If the first dose is administered 5 or more days before age 6 months, repeat the dose on or after the date the recipient reaches 6 months.*
	• Recipients transitioning from age 4 years to 5 years who start a 3-dose Pfizer-BioNTech series with updated (2023–2024 Formula) vaccine for ages 6 months–4 years (yellow cap; yellow label) and incorrectly receive updated (2023–2024 Formula) vaccine for ages 5–11 years (blue cap; blue label) for either dose 2 or 3	• Do not repeat dose 2 or 3. • If the error occurred with dose 2, administer updated (2023–2024 Formula) Pfizer-BioNTech vaccine for ages 6 months–4 years (yellow cap; yellow label) for the third dose at least 8 weeks after the second dose.
Product and dosage	• Higher-than-authorized dose administered (e.g., incorrect dose volume, incorrect product resulting in higher-than-authorized dose)	• Do not repeat dose.†
	• Lower-than-authorized dose administered (e.g., leaked out of the syringe, equipment failure, recipient pulled away, incorrect product resulting in lower-than-authorized dose)	• Repeat dose immediately (no minimum interval).‡§ • However, if a half-volume dose of vaccine is administered to a recipient recommended for the full volume, another half-volume dose can be administered on the same clinic day, and the 2 doses can count as 1 full dose.
	• Bivalent mRNA vaccine dose administered for an updated (2023–2024 Formula) mRNA dose	• Repeat the dose using an age-appropriate updated (2023–2024 Formula) mRNA vaccine. • If dose given in error was the first dose, space repeat dose by at least 4 weeks; for other doses, space repeat dose after the dose given in error by at least the minimum interval (Table 1 and Table 2).§

Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates | CDC


Key Takeaway

KEY COVID-19 VACCINE RECOMMENDATION TAKEAWAYS

- **Bivalent mRNA COVID-19 vaccines are no longer recommended in the U.S.**
- ACIP recommends that everyone 6 months and older get an updated 2023-2024 COVID-19 vaccine this fall and winter
- Use the following resources to determine what your patient needs:
  - COVID-19 vaccines 2023-2024 NOT immunocompromised (cdc.gov)
  - COVID-19 vaccines 2023-2024 ARE immunocompromised (cdc.gov)
  - Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- Use the following resources for storage and handling information:
  - Pfizer-BioNTech COVID-19 Vaccine At A Glance: Updated 2023-2024 Formula (cdc.gov)
  - Moderna COVID-19 Vaccine At A Glance: Updated 2023-2024 Formula (cdc.gov)
  - SPIKEVAX 12+ Package Insert (fda.gov)
  - Package Insert – COMIRNATY 12+ (fda.gov)
  - Pfizer EUA Healthcare 6m-11y 9.11.2023 (michigan.gov)
  - Moderna EUA Healthcare 6m-11y 09.11.2023 (michigan.gov)
  - Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) Fact Sheet for Healthcare Providers Administering Vaccine (michigan.gov)



Next "Noontime Knowledge": TBD

Thank You!

Questions email:
checcimms@michigan.gov